IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KAREN LARSON, *Plaintiff*, v. ABBOTT LABORATORIES, *et al.*, *Defendants*.	Civil Action No. ELH-13-00554

MEMORANDUM OPINION

Karen Larson, as guardian for her brother, Kraig Larson, sued several defendants in the Circuit Court for Baltimore City, alleging that Mr. Larson suffered severe and permanent brain damage proximately caused by his use of the prescription drug Adalimumab, commonly known as HUMIRA. *See* Complaint, ECF 2. According to Ms. Larson, HUMIRA increases the risk of severe injury or death from infection when taken by individuals with immunodeficiency, such as human immunodeficiency virus ("HIV"). *Id.* ¶ 14. Mr. Larson, a former space engineer, is HIV positive ("HIV+"), and the drug was prescribed to him for the treatment of his psoriasis.[1] *Id.* ¶¶ 4, 38.

In particular, Ms. Larson sued Abbott Laboratories ("Abbott"), the manufacturer of HUMIRA, and Harrison & Star ("H&S"), a healthcare marketing agency that marketed HUMIRA from 2005 through 2009 (collectively, the "Pharmaceutical Defendants"). *Id.* ¶ 5–7. She also sued Monte S. Meltzer, M.D., who prescribed HUMIRA in 2010 to Mr. Larson, and Monte S. Meltzer, M.D., LLC; the Union Memorial Hospital in Baltimore, at which Dr. Meltzer

[1] Psoriasis is a condition that causes skin cells to build up rapidly on the surface of the skin, creating itchy, red scales. Complaint ¶ 41.

worked; Dr. Ellen Yang, M.D., an infectious disease physician who monitored Mr. Larson's "HIV" condition; and Annapolis Infectious Disease Associates, L.L.P., for whom Dr. Yang worked (collectively, the "Medical Defendants"). *Id.* ¶ 92.

As to Abbott, plaintiff alleges strict liability failure to warn, negligent failure to warn, and breach of implied warranties. *Id.* ¶¶ 62–76. She also seeks to recover punitive damages. *Id.* ¶¶ 77–78. As to both Abbott and H&S, plaintiff alleges common law misrepresentation and violations of Maryland's Consumer Protection Act, Md. Code (2012), § 13-301 *et seq*. of the Commercial Law Article. *Id.* ¶¶ 79–90. With respect to the Medical Defendants, Ms. Larson alleges medical malpractice, negligence, and lack of informed consent. *Id.* ¶¶ 91–115.

As discussed, *infra*, Ms. Larson had previously sued the Medical Defendants, but she subsequently dismissed that suit.[2] In a subsequent suit, filed on January 2, 2013, she added the Pharmaceutical Defendants. On February 20, 2013, Abbott filed a Notice of Removal, asserting that this Court has federal question jurisdiction under 28 U.S.C. § 1331 and diversity jurisdiction under 28 U.S.C. § 1332. ECF 1. Because I was unable to determine from the Notice of Removal whether this Court has subject matter jurisdiction, I directed the parties to brief the matter. ECF 24. The Pharmaceutical Defendants argue in their Memorandum of Law ("Memo," ECF 30) that this Court has both diversity jurisdiction and federal question jurisdiction. In their Response ("Med. Resp.," ECF 32), the Medical Defendants assert that this Court has federal question jurisdiction, but not diversity jurisdiction. Plaintiff filed a Motion to Remand ("Larson Mot.,"

[2] Union Memorial Health Services, Inc. was a defendant in the prior suit, but is not named as a defendant in the present suit.

ECF 27), accompanied by a Memorandum (ECF 27-1), and a Response in Support of Remand ("Larson Resp.," ECF 33), arguing that this Court lacks subject matter jurisdiction. No hearing is necessary to resolve the matter. *See* Local Rule 105.6. For the reasons that follow, I conclude that this Court lacks subject matter jurisdiction. Therefore, I will remand the case to the Circuit Court for Baltimore City.

Factual Summary[3]

Testing and Marketing of HUMIRA

HUMIRA is an immunosuppressant and tumor necrosis factor inhibitor ("TNF Inhibitor")[4] manufactured by Abbott. Complaint ¶ 11. Following a series of clinical trials, which did not include HIV+ individuals, the Food & Drug Administration ("FDA") approved HUMIRA in December 2002 for treatment of rheumatoid arthritis. *Id.* ¶ 12, 13. Abbott launched HUMIRA in 2003. *Id.* ¶ 15. From 2005 until early 2009, HUMIRA was marketed by H&S. *Id.* ¶ 7.

Abbott ran additional clinical trials in 2003 and 2004 to establish the efficacy of HUMIRA to treat some forms of psoriatic arthritis. *Id.* ¶ 16. However, these trials did not include any known HIV+ patients. *Id*. According to Ms. Larson, the prescribing information distributed by Abbott emphasized HUMIRA's effectiveness while understating its risks. *Id*. In

[3] The facts are gleaned largely from the Complaint.

[4] TNF inhibitors suppress the body's natural inflammatory response mechanism. *Concise Medical Dictionary*, Oxford University Press (8th ed. 2010).

particular, the prescribing information did not warn that HUMIRA had not been proven safe for use by HIV+ patients. *Id.*

In 2005, HUMIRA sales exceeded one billion dollars; in 2006 they exceeded two billion dollars; and in 2007 they exceeded three billion dollars. *Id.* ¶ 19. Ms. Larson alleges that throughout this time period, "Abbott over-promoted HUMIRA through misleading and deceptive communications that were intended to stimulate demand for HUMIRA notwithstanding the drug's dangerous propensities, including to Kraig Larson and other members of the HIV+ community." *Id.* ¶ 20.

On January 18, 2008, the FDA approved the use of HUMIRA for "'adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.'" *Id.* ¶ 23. In approving HUMIRA, the FDA noted that HUMIRA "'poses a serious and significant public health concern relating to increased risk for serious infections,'" and it required Abbott to conduct continued testing to "'assess the incidence of serious adverse events . . . .'" *Id.* ¶ 24.

In early 2008, the Pharmaceutical Defendants began promoting HUMIRA to dermatologists as a treatment for psoriasis. *Id.* ¶¶ 25, 28. As part of its marketing efforts, Abbott hired Dr. Meltzer to make presentations about HUMIRA to other dermatologists. *Id.* ¶ 36. In making the presentations, Dr. Meltzer allegedly relied on information about HUMIRA provided to him by Abbott. *Id.* Ms. Larson alleges, *id.* ¶ 37:

> The information Abbott provided to Dr. Meltzer overall was inadequate and misleading, resulting in Dr. Meltzer erroneously concluding that if an HIV+

> patient with moderate to severe psoriasis that cannot be controlled by topical medications or phototherapy reports both being under the care of an infectious disease doctor and not being on an antiretroviral medication, it is acceptable and reasonably safe to treat that patient with HUMIRA injections without consulting his infectious disease doctor and without knowing his patient's CD4[5] count of viral load.

Abbott also placed an advertisement in the *Post Meeting News*, which was distributed in February 2008 after the 66th annual meeting of the American Academy of Dermatology ("AAD"). *Id.* ¶¶ 25, 27. The advertisement stated that HUMIRA had been approved for "moderate to severe chronic plaque psoriasis," but did not state that HUMIRA was only approved for use "when other systemic therapies are medically less appropriate." *Id.* ¶ 28; *see id.* ¶ 23. Dr. Meltzer is a member of AAD, *id.* ¶ 26, and, according to Ms. Larson, he received a copy of this advertisement and "trusted the truth of the message to his own detriment and the detriment of Kraig Larson." *Id.* ¶ 29.

The FDA sent a warning letter to Abbott on December 16, 2008, notifying Abbott that its advertisement in the *Post Meeting News* was misleading. *Id.* ¶ 27. The warning letter stated, in part, *id.* ¶ 28:

> The AAD Post Meeting News Ad is misleading because it suggests that HUMIRA is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience. . . . This claim misleadingly suggests that HUMIRA is approved for any patient with moderate to severe chronic plaque psoriasis. . . . HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. Due to the drug's high risk profile, the use of HUMIRA in plaque psoriasis needs to be very carefully considered, a message not conveyed in the ad. . . .

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[5] CD4 cells are white blood cells that fight infection. *Id.* ¶ 40.

> The overall effect of this presentation undermines the communication of important risk information, minimizing the risks associated with HUMIRA and misleadingly suggesting that HUMIRA is safer than has been demonstrated.

Soon after the FDA issued the warning letter, Abbott fired H&S. *Id.* ¶ 30.

Academic Research on HUMIRA

In her Complaint, Ms. Larson refers to several academic papers published between 2004 and 2009, which highlighted the risks posed to HIV+ individuals by TNF inhibitors. Ms. Larson alleges that Abbott knew or should have known of such research. *Id.* ¶¶ 18, 22, 32, 34. Yet, Abbott never included the papers' conclusions in its communications about HUMIRA; never included information about the risks of HUMIRA to HIV+ patients in its communications with doctors; never indicated which patients, if any, were proper candidates for the use of HUMIRA; never provided information as to the necessary precautions for use of the medication; and never conducted clinical trials to determine whether HUMIRA was safe for HIV+ patients. *Id.*

For example, Ms. Larson identified a 2004 paper by Dee Dee Wu, M.D., of New York's Hospital for Special Surgery, in which Dr. Wu stated that "'it is reasonable to conclude that anti-TNF agents can be used with great caution in HIV+ patients with significant morbidity from a TNF-a-mediated illness.'" *Id.* ¶ 17. On January 15, 2008, rheumatologist Jon Giles, M.D. published a paper for the Johns Hopkins Arthritis Center that, among other things, pointed out that clinical practice "'dictated that [TNF inhibitor therapy] [should not be] initiated in patients with a CD4 count below 200 or a viral load[6] greater than 60,000 copies.'" *Id.* ¶ 22 (second alternation in Complaint); *see also id.* ¶ 21. In April 2009, dermatologist Jason J. Emer, M.D., of

[6] The viral load measures the amount of active HIV in the blood. *Id.* ¶ 40.

the Mount Sinai School of Medicine in New York City, published a paper in which he concluded: "'TNF inhibition in HIV should be reserved for highly selected patients who have failed other treatment options and are well controlled under antiretroviral therapy until the potential for long-term effects . . . have been more clearly determined.'" *Id.* ¶ 31. The Medical Board of the National Psoriasis Foundation published a paper in August 2009, titled "Psoriasis in Patients with HIV Infection," which stated that "'patients with HIV-associated psoriasis should be followed up carefully for potential adverse events with regular monitoring of the CD4 counts and HIV viral loads, and regular consultation with an infectious disease specialist.'" *Id.* ¶ 33.

Mr. Larson's Use of HUMIRA

Kraig Larson was diagnosed as HIV+ in 2004. *Id.* ¶ 38. He also has psoriasis. *Id.* ¶ 41. From 2004 through 2010, Mr. Larson's HIV status was monitored by Dr. Yang, an infectious disease physician with Annapolis Infectious Disease Associates, LLP. *Id.* ¶ 39. On or about October 21, 2009, Dr. Yang evaluated Mr. Larson and noted that his psoriasis had worsened since the last time she examined him. *Id.* ¶ 42. However, she told Mr. Larson that his HIV remained asymptomatic and stable. *Id.*

Dr. Yang conducted a blood draw on Mr. Larson on October 21, 2009. *Id.* ¶ 43. Subsequent blood tests indicated that Mr. Larson's CD4 count was 266 and his viral load was 138,500 copies. *Id.* Previously, Mr. Larson's lowest reported CD4 count was 434 and his

highest viral load was 53,143 copies. *Id.* According to plaintiff, it was "Dr. Yang's duty to promptly review and clinically correlate the change in Mr. Larson's CD4 count and viral load in November of 2009 and place Mr. Larson on antiretroviral medication." *Id.* ¶ 44. However, Dr. Yang did not place Mr. Larson on antiretroviral medication. *Id.*

In early 2010, Mr. Larson, who had seen advertisements promoting the use of HUMIRA to treat psoriasis, made an appointment with Dr. Meltzer. *Id.* ¶ 45. Mr. Larson had "learned about" Dr. Meltzer "via the MedStar Union Memorial Hospital website, at which site Union Memorial Hospital represents that Dr. Meltzer's specialty is dermatology." *Id.* Dr. Meltzer's office is located on the campus of Union Memorial Hospital. *Id.* ¶ 49.

Dr. Meltzer learned from Mr. Larson that he (Larson) is HIV positive. *Id.* ¶ 52. Nonetheless, he prescribed HUMIRA. *Id.* ¶ 51. Dr. Meltzer did not inform Mr. Larson that there was no evidence to establish the safety of HUMIRA for HIV+ patients. Plaintiff contends that Dr. Meltzer "affirmatively misinformed [Mr. Larson] that HUMIRA was being safely used by HIV+ patients." *Id.* ¶ 53. According to plaintiff, Dr. Meltzer claims that he reviewed the prescribing information provided by Abbott with Mr. Larson, but "the black box warning does not discuss using HUMIRA on HIV+ patients, the other warnings and instructions make no mention of this either, no contraindications were listed and the words HIV or AIDS do not even appear in the document." *Id.* ¶ 54.

Although HUMIRA contained a warning that it should not be used in patients with an "active" infection, Dr. Meltzer concluded that Mr. Larson did not have an "active" infection. *Id.*

Plaintiff counters that Dr. Meltzer failed to consult with Dr. Yang or inquire about Mr. Larson's CD4 count or viral load before prescribing HUMIRA. *Id.* ¶¶ 51–52. To the contrary, she asserts that Dr. Meltzer reassured Mr. Larson that the manufacturer "did not discourage use of HUMIRA for HIV+ patients like Mr. Larson." *Id.* ¶ 54.

Mr. Larson began taking HUMIRA via injection on January 15, 2010. *Id.* ¶ 56. In April 2010, Mr. Larson became "critically ill with progressive multifocal leukoencephalopathy ("PML"),"[7] *id.* ¶ 57, which led to "serious and permanent brain damage and other injuries." *Id.* ¶ 4; *see id.* ¶ 59. As a result of his injuries, Mr. Larson "will never work again and requires 24-hour round the clock medical care to perform the activities of daily living." *Id.* ¶ 60. Ms. Larson alleges that Mr. Larson's injuries were caused by his use of HUMIRA. *Id.* ¶¶ 57, 59.

Procedural History

In October 2011, Ms. Larson filed suit against Dr. Meltzer in the Circuit Court for Baltimore City, alleging medical malpractice and negligence. *See* 2011 Complaint, ECF 1-2 at 1. She amended her complaint in July 2012, adding defendants Union Memorial Hospital, Union Memorial Health Services, Inc., Dr. Ellen Yang, and Annapolis Infectious Disease Associates, LLP. *See* 2012 Amended Complaint, ECF 1-2 at 29. Ms. Larson also added a claim for "Lack of Informed Consent." *Id.* at 37. However, in November 2012, Ms. Larson and the defendants

[7] "PML is an infection caused by the spread of the JC Virus (JCV), which progressively attacks the white matter of the brain at multiple locations." *Id.* ¶ 58. Plaintiff alleges that JVC is usually harmless, but its use by someone with immunosuppression, such as from use of HUMIRA, coupled with a CD4 count and viral load similar to that of Kraig Larson, can lead to PML. *Id.*

filed a joint "Stipulation of Dismissal Without Prejudice." *See* Stipulation, ECF 1-6; Case Information, ECF 1-7 at 10.

Thereafter, in January 2013, Ms. Larson again filed suit in the Circuit Court for Baltimore City. Complaint, ECF 2. In addition to re-asserting her claims against the Medical Defendants, she added the Pharmaceutical Defendants and the claims against them that were described above. *Id.* Thereafter, as noted, Abbott filed a Notice of Removal, claiming that jurisdiction is proper under 28 U.S.C. § 1331 and 28 U.S.C. § 1332. ECF 1. At issue is the question of whether this Court has subject matter jurisdiction over any of the claims against any of the parties.

Discussion

Federal courts are courts of limited jurisdiction and "may not exercise jurisdiction absent a statutory basis." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005). "A court is to presume, therefore, that a case lies outside its limited jurisdiction unless and until jurisdiction has been shown to be proper." *United States v. Poole*, 531 F.3d 263, 274 (4th Cir. 2008) (citing *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)). Moreover, a federal court has "an independent obligation to determine whether subject-matter jurisdiction exists, even when no party challenges it." *Hertz Corp. v. Friend*, 559 U.S. 77, 94 (2010).

Congress has conferred jurisdiction on the federal courts in several ways. To provide a federal forum for plaintiffs who seek to vindicate federal rights, Congress has conferred on the district courts original jurisdiction over civil actions that arise under the Constitution, laws, or

treaties of the United States. *Exxon Mobil Corp.*, 545 U.S. at 552; 28 U.S.C. § 1331. *See also* U.S. Constitution Art. III, § 2 ("The Judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made. . . .") Moreover, 28 U.S.C. § 1367(a) grants district courts "supplemental jurisdiction over all other claims that are so related to claims in the action within [the courts'] original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

In addition, "Congress . . . has granted district courts original jurisdiction in civil actions between citizens of different States, between U.S. citizens and foreign citizens, or by foreign states against U.S. citizens," so long as the amount in controversy exceeds $75,000. *Exxon Mobil Corp.*, 545 U.S. at 552; *see* 28 U.S.C. § 1332. This so-called diversity jurisdiction "requires complete diversity among parties, meaning that the citizenship of every plaintiff must be different from the citizenship of every defendant." *Cent. W. Virginia Energy Co., Inc. v. Mountain State Carbon, LLC*, 636 F.3d 101, 103 (4th Cir. 2011); *see Strawbridge v. Curtiss*, 7 U.S. 267 (1806).

If a plaintiff files suit in state court with respect to a matter over which the "the district courts of the United States have original jurisdiction," the defendant generally may remove the case to federal district court. 28 U.S.C. § 1441(a). With respect to cases removed to federal court from state court, 28 U.S.C. § 1447(c) provides: "If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded."

Ms. Larson is a citizen of New Jersey. Complaint ¶ 3. However, she brings this suit as the legal representative of her brother, who is a citizen of Maryland. *Id.* Section 1332(c)(2) of Title 28 provides: "[T]he legal representative of an infant or incompetent shall be deemed to be a citizen only of the same State as the infant or incompetent." Accordingly, the parties agree that, for purposes of this suit, Ms. Larson is deemed a citizen of Maryland. Complaint ¶ 3; Notice of Removal at 9 n.2. Abbott is a citizen of Illinois, H&S is a citizen of Delaware, Dr. Meltzer is a citizen of the District of Columbia, and the rest of the Medical Defendants—like Ms. Larson—are citizens of Maryland. Notice of Removal ¶¶ 21–22; Response to Standing Order, ECF 25 ¶ 2.

Ms. Larson filed her suit in state court, asserting claims based not on federal law, but rather under Maryland law. Nevertheless, the Pharmaceutical Defendants argue that this Court has both federal question jurisdiction and diversity jurisdiction over the claims against them. First, they argue that this Court has federal question jurisdiction under 28 U.S.C. § 1331, despite plaintiff's characterization of her claims, because "adjudicating the Plaintiff's claim that Abbott should have conducted clinical tests on HIV+ patients and included specific warnings in its labels *necessarily* involves the interpretation and application of a wide range of important federal statutes and rules." Memo at 2 (emphasis in original). Second, they argue that this Court has diversity jurisdiction under 28 U.S.C. § 1332, notwithstanding the lack of complete diversity with regard to the Medical Defendants, because "Abbott and Harrison & Star were fraudulently *mis*joined to the Medical Malpractice Defendants," and thus the Court "may disregard for

jurisdictional purposes" the citizenship of the Medical Defendants. *Id.* (emphasis in original). I address these contentions in turn.

A. Federal Question Jurisdiction

As noted, Congress has authorized the federal district courts to exercise original jurisdiction in "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. The question is whether this case arises under federal law.

As the Supreme Court has observed, "There is no 'single, precise definition'" of the "concept" of federal question jurisdiction. *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (citation omitted). Notably, "'the phrase "arising under" masks a welter of issues regarding the interrelation of federal and State authority and the proper management of the federal judicial system.'" *Id.* (citation omitted). "Most directly, a case arises under federal law when federal law creates the cause of action asserted." *Gunn v. Minton*, ___ U.S. ___, 133 S. Ct. 1059, 1064 (2013); *see Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for Southern Cal.*, 463 U.S. 1, 9 (1983).

The "'presence or absence of federal-question jurisdiction is governed by the "well-pleaded complaint rule," which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint.'" *Rivet v. Regions Bank of La.*, 522 U.S. 470, 475 (1998) (citation omitted). Accordingly, it is "settled law that a case may not be removed to federal court on the basis of a federal defense, including the defense of pre-emption, even if the defense is anticipated in the plaintiff's complaint, and even if

both parties concede that the federal defense is the only question truly at issue." *Caterpillar Inc. v. Williams*, 482 U.S. 386, 393 (1987).

Nevertheless, in a "special and small" category of cases, state law claims can give rise to federal question jurisdiction. *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006). To fall within this category, the state law claims must "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). In *Gunn*, the Supreme Court explained, 133 S. Ct. at 1065 (quoting *Grable*, 545 U.S. at 313–14):

> [F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. Where all four of these requirements are met . . . jurisdiction is proper because there is a "serious federal interest in claiming the advantages thought to be inherent in a federal forum," which can be vindicated without disrupting Congress's intended division of labor between state and federal courts.

Ms. Larson lodges a variety of claims against the Pharmaceutical Defendants based on injuries her brother allegedly sustained from the use of HUMIRA. They are strict product liability (Count I); negligence (Count II); breach of implied warranty (Count III); violation of the Maryland Consumer Protection Act's deceptive trade practice provisions (Count V); and common law misrepresentation (Count VI). She also seeks punitive damages (Count IV). The Pharmaceutical Defendants do not argue that federal law creates any of these causes of action.

Thus, the question is whether these claims fit within the "special and small" category of cases described in *Grable* and *Gunn*.

In arguing that this case satisfies the first element of the *Grable* test, *i.e.*, that it "necessarily raises" a federal issue, the Pharmaceutical Defendants note that clinical testing and drug labeling are heavily regulated by federal law. Therefore, according to the Pharmaceutical Defendants, "resolving the question of whether Abbott improperly failed to conduct clinical trials on a particular class of patients and whether its labels were inadequate as a result necessarily raises a substantial federal issue." Memo at 2.

In their Memorandum, the Pharmaceutical Defendants set out in detail the federal laws and regulations governing the approval process and labeling requirements for new drugs. Memo at 3–8. They also point to assorted portions of the Complaint to support their position, including that plaintiff "seeks to second guess the regulatory process," *id.* at 9; that plaintiff is "attacking the federal regulatory process," *id.*; that plaintiff alleges that Abbott violated FDA regulations, *id.* at 10; that plaintiff "intends to attack . . . FDA's decision to approve HUMIRA without clinical trials on HIV+ patients," *id.* at 13; and that plaintiff's claim "requires the interpretation and application of a plethora of federal laws and regulations that are administered by a federal agency." *Id.* at 11.

In response, plaintiff posits that the Pharmaceutical Defendants have mischaracterized her Complaint. She observes that she has not alleged any violation of federal law, and contends that her claims "do not require proof of any federal element." Larson Resp. at 14; *see id.* at 11.

I have searched the Complaint in vain for the assaults on federal regulations described by the Pharmaceutical Defendants. In the Complaint, Ms. Larson does not question Abbott's compliance with federal regulations, nor does she challenge the wisdom of those regulations. Although the Complaint alleges that Abbott's clinical trials "did not include [HIV+] individuals," *id.* ¶ 13, it does not allege that the omission of HIV+ patients was contrary to federal law. *But see* Memo at 10 (stating that "the plaintiff's argument is that Abbott was obligated to test its drug on [HIV+ individuals]"). Similarly, the Complaint alleges deficiencies in the information disseminated for prescribing HUMIRA, such as understating HUMIRA's risks. *See, e.g.*, Complaint ¶ 63(b). But, it does not allege that the information violated complex federal drug labeling requirements, or that HUMIRA was mislabeled under federal law. *See PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567, 2572 (2011) (holding that plaintiff's state law tort claims against generic drug manufacturers were preempted by federal labeling requirements); *Caterpillar Inc.*, 482 U.S. 393. *But see Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (holding that plaintiff's common law claims against drug's manufacturer were not preempted by federal labeling requirements). And *see* Memo at 9 (asserting that "this Court will have to determine whether the failure to include such a warning was improper . . . *under federal law and FDA regulations*" (emphasis in original)). Indeed, the claimed bases of liability do not refer to, incorporate, or otherwise mention any federal law or regulation. *See* Complaint ¶¶ 63(a)–(l), 68(a)–(l), 74(a)–(l), 80, 81, 84–89. To the contrary, plaintiff seeks to impose liability on the Pharmaceutical Defendants without regard to their compliance *vel non* with federal laws

and regulations. Nor is there a private right of action under the Federal Food, Drug, and Cosmetic Act ("FDCA"), through which plaintiff could claim that HUMIRA's labeling violated federal regulations. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); 21 U.S.C. § 337 (authorizing enforcement proceedings only by the United States and, under some circumstances, by a state).

The Pharmaceutical Defendants suggest that the Complaint is that it alleges some kind of cause-effect relationship between the Pharmaceutical Defendants' failure to conduct clinical studies with HIV+ patients and their subsequent failure to warn of the dangers HUMIRA posed to HIV+ individuals. For example, the Pharmaceutical Defendants state that plaintiff "alleges that without clinical tests, HUMIRA's label could not adequately warn of the alleged 'special danger' the drug poses to HIV+ patients." Memo at 8. Similarly, they state: "Plaintiff's Complaint asserts that Abbott failed to warn of the dangers associated with an HIV+ patient taking HUMIRA *because Abbott did not conduct clinical trials on HIV+ patients.*" *Id.* at 3 (emphasis in original); *see also id.* at 2, 8–9, 12.

Although plaintiff alleges that HUMIRA's prescribing information was inadequate under State law, and complains that no clinical tests were performed on HIV+ individuals, she does not claim that the prescribing information was inadequate *because* of the omission in clinical testing. Rather, she provides at least two reasons why the Pharmaceutical Defendants "knew or should have known" about HUMIRA's risks, even without clinical testing. Specifically, Ms. Larson alleges that Abbott "knew or should have known" of several academic papers discussing the

risks that TNF inhibitors pose to HIV+ individuals. *E.g.*, *id.* ¶ 32. And, she points out that the FDA's approval letter of January 18, 2008, highlighted the dangers that HUMIRA poses to patients, including "serious infections" and "autoimmune reactions." *Id.* ¶ 24.

Simply put, the Complaint that the Pharmaceutical Defendants described is not the one that Ms. Larson filed. Saying it repeatedly does not make it so. *Cf.* Lewis Carroll, *The Hunting of the Snark* 3 (1876) ("I have said it thrice: What I tell you three times is true.").

Moreover, the Pharmaceutical Defendants do not rely on the doctrine of complete preemption, under which a federal district court may assert jurisdiction over a claim ostensibly grounded in state law when that claim "is in reality based on federal law." *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003). To remove an action on the basis of complete preemption, "a removing defendant must show not only that the defendant's state law claim is cognizable as a federal claim, but also that Congress clearly intended the federal claim to 'provide *the exclusive* cause of action for claims of overwhelming national interest'" *Barbour v. Intern. Union*, 640 F.3d 599, 631 (4th Cir. 2011) (en banc) (emphasis in original) (citation and quotation marks omitted), *abrogated on other grounds by* 28 U.S.C. § 1446(b)(2)(B).

Even assuming that the Pharmaceutical Defendants rely on preemption, the State court has the power to determine the propriety of such an affirmative defense. It can resolve whether plaintiff's claims are preempted by federal regulations governing the approval and marketing of prescription drugs. In any event, the fact that a claim may implicate the testing and marketing of a pharmaceutical drug is not, by itself, sufficient to confer federal question jurisdiction.

Merrell Dow Pharmaceuticals, 478 U.S. 804, provides guidance. There, two sets of plaintiffs filed suit in state court, alleging, *inter alia*, that a pharmaceutical company was negligent in its labeling of a prescription drug. *Id.* at 805–6. They claimed that the drug's labeling violated the FDCA, because the labeling did not provide adequate warnings, and they sought to use that violation to establish a rebuttable presumption of negligence under state law. *Id.* at 805-06. The company removed the case to federal court, arguing that plaintiff's reliance on the company's alleged violation of a federal statute conferred federal-question jurisdiction on the district court. *Id.* at 813–14.

The Supreme Court disagreed. It considered "whether the incorporation of a federal standard in a state-law private action, when Congress has intended that there not be a federal private action for violation of that federal standard, makes the action one 'arising under the Constitution, laws, or treaties of the United States[.]'" *Id.* at 805 (citation omitted). It concluded that the state court actions against the drug manufacturer did not present a substantial federal question so as to confer federal jurisdiction. *Id.* at 817. The Court reasoned that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under the Constitution, laws, or treaties of the United States.'" *Id.* at 817 (quoting 28 U.S.C. § 1331). Therefore, removal was improper.

Like the plaintiffs in *Merrell Dow*, Ms. Larson seeks to hold the Pharmaceutical Defendants liable in connection with warnings that were allegedly inadequate. However, unlike

the plaintiffs in *Merrell Dow*, Ms. Larson does not allege a violation of the FDCA, nor does she attempt to rely on a violation of the FDCA as an element of her claim. Indeed, she expressly disclaims any allegation that the Pharmaceutical Defendants violated federal law. *See* Larson Resp. at 9. If a claim expressly relying on an alleged violation of a federal statute is insufficient to confer federal question jurisdiction, *see Merrell Dow*, 478 U.S. at 817, then surely an analogous claim that does *not* allege failure to comply with federal law is also insufficient.

Even assuming, *arguendo*, that a federal issue is raised by plaintiff's Complaint, the Pharmaceutical Defendants cannot show that the issue is "actually disputed." As plaintiff states, "there is nothing disputed in the federal statutory and regulatory realm because the Plaintiff does not allege that the law *required* HIV+ patients to be included in the HUMIRA clinical trials." Larson Resp. at 15.

Accordingly, I conclude that this Court does not have federal question jurisdiction under 28 U.S.C. § 1331. Therefore, I will proceed to determine whether subject matter jurisdiction exists under 28 U.S.C. § 1332.

B. Diversity Jurisdiction

As discussed, diversity jurisdiction under 28 U.S.C. § 1332 "requires complete diversity among parties, meaning that the citizenship of every plaintiff must be different from the citizenship of every defendant." *Cent. W. Virginia Energy Co., Inc.*, *supra*, 636 F.3d at 103. "When a plaintiff files in state court a civil action over which the federal district courts would

have original jurisdiction based on diversity of citizenship, the defendant or defendants may remove the action to federal court, 28 U.S.C. § 1441(a), provided that no defendant 'is a citizen of the State in which such action is brought.'" *Caterpillar Inc. v. Lewis*, 519 U.S. 61, 68 (1996) (quoting 28 U.S.C. § 1441(b)).

The Pharmaceutical Defendants concede that both plaintiff and several of the Medical Defendants are citizens of Maryland. Ordinarily, such lack of complete diversity would defeat this Court's diversity jurisdiction. *See* 28 U.S.C. § 1441(b). However, the Pharmaceutical Defendants contend: "Plaintiff has fraudulently misjoined both Abbott and Harrison & Star to the Medical Malpractice Defendants." Memo at 18. As a result, they claim that "the citizenship of the Medical Malpractice Defendants is not considered for purposes of establishing diversity jurisdiction." Notice of Removal ¶ 23.

To address properly the Pharmaceutical Defendants' argument that they were "fraudulently misjoined," it is important to distinguish between the widely accepted doctrine of "fraudulent joinder" and the more controversial doctrine of "fraudulent *mis*joinder."

The doctrine of fraudulent joinder has been expressly adopted by the Fourth Circuit. *See Mayes v. Rapoport*, 198 F.3d 457, 464 (4th Cir. 1999). The fraudulent joinder doctrine prevents a plaintiff from adding a non-diverse defendant solely for the purpose of defeating federal diversity jurisdiction. Fraudulent joinder occurs when "'there is *no possibility* that the plaintiff would be able to establish a cause of action against the in-state defendant in state court; or [when] there has been outright fraud in the plaintiff's pleading of jurisdictional facts.'" *Id.*

(quoting *Marshall v. Manville Sales Corp.*, 6 F.3d 229, 232 (4th Cir. 1993)) (emphasis in *Marshall*). In such a case, the doctrine permits a court to "disregard, for jurisdictional purposes, the citizenship of certain non-diverse defendants, assume jurisdiction over a case, dismiss the nondiverse defendants, and thereby retain jurisdiction." *Mayes*, 198 F.3d at 464; *accord Schur v. L.A. Weight Loss Centers, Inc.*, 577 F.3d 752, 763 (7th Cir. 2009); *Balt. Cnty. v. Cigna Healthcare*, 238 F. App'x 914, 920 (4th Cir. 2007); *In re Briscoe*, 448 F.3d 201, 216 (3d Cir. 2006).

The doctrine of "fraudulent misjoinder" or "procedural misjoinder" was also created to prevent plaintiffs from improperly defeating diversity jurisdiction. *See Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353 (11th Cir. 1996) (creating the doctrine), *abrogated on other grounds by Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000). But, it is not as widely accepted as the doctrine of fraudulent joinder. *See Rutherford v. Merck & Co.*, 428 F. Supp. 2d 842, 852 (S.D. Ill. 2010) ("[E]normous judicial confusion [has been] engendered by the [fraudulent misjoinder] doctrine."). Courts have found fraudulent misjoinder when a plaintiff includes "claims against certain defendants [that], while provable, have no real connection to the claims against other defendants in the same action and were only included in order to defeat diversity jurisdiction and removal." *Stephens v. Kaiser Found. Health Plan of the Mid-Atl. States, Inc.*, 807 F. Supp. 2d 375, 379 (D. Md. 2011). In other words, a plaintiff has fraudulently misjoined a defendant whose presence defeats diversity jurisdiction when the claims against that defendant, although with merit, are not connected to the claims against the other, diverse defendants. *Id.*

As with fraudulent joinder, the fraudulent misjoinder doctrine permits federal district courts "to disregard the citizenship of non-diverse parties and retain jurisdiction." *Id.*

The Fourth Circuit has not addressed the doctrine of fraudulent misjoinder, and the status of the doctrine among district courts is muddled. As an initial matter, district courts in this Circuit disagree about whether to adopt the doctrine. *Compare Stephens*, 807 F. Supp. 2d at 378–80 (adopting fraudulent misjoinder doctrine), *and Burns v. W. S. Life Ins. Co.*, 298 F. Supp. 2d 401, 403 (S.D. W. Va. 2004) (same), *with Palmetto Health Alliance v. S. Carolina Elec. & Gas Co.*, Civ. No. JFA-11-2060, 2011 WL 5027162, *2 (D.S.C. Oct. 21, 2011) (declining to adopt fraudulent misjoinder doctrine), *and Beaty v. Bridgestone Americas Tire Operations, LLC*, Civ. No. RBH-10-3303, 2011 WL 939001, *3–4 (D.S.C. Mar. 16, 2011) (same). District courts in other circuits similarly have not reached a consensus. *See Geffen v. Gen. Elec. Co.*, 575 F. Supp. 2d 865, 870 (N.D. Ohio 2008) (noting the "conflicting case law" on the subject).

Among the courts that have adopted the fraudulent misjoinder doctrine, further disagreement exists over its contours. In *Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d at 1360, the Eleventh Circuit stated:

> Misjoinder may be just as fraudulent as the joinder of a resident defendant against whom a plaintiff has no possibility of a cause of action. A defendant's "right of removal cannot be defeated by a fraudulent joinder of a resident defendant having no real connection with the controversy." *Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921). . . . We do not hold that mere misjoinder is fraudulent joinder, but we do agree with the district court that Appellants' attempt to join these parties is so egregious as to constitute fraudulent joinder.

Some district courts, picking up on the last line of this passage, have declined to find fraudulent misjoinder in the absence of egregiousness or "'something more'" than mere misjoinder. *Wyatt v. Charleston Area Med. Ctr., Inc.*, 651 F. Supp. 2d 492, 496 (S.D. W. Va. 2009) (quoting *In re Bridgestone/Firestone, Inc.*, 260 F. Supp. 2d 722, 728 (S.D. Ind. 2003)). Others, including the majority of district courts within the Fourth Circuit that have adopted the doctrine, have declined to impose an egregiousness requirement on the misjoinder analysis. *See, e.g.*, *Stephens*, 807 F. Supp. 2d at 381; *Hughes v. Sears, Roebuck and Co.*, Civ. No. JPB-09–93, 2009 WL 2877424, at *5 (N.D. W. Va. Sept. 3, 2009); *Burns*, 298 F. Supp. 2d at 403; *see generally* E. Farish Percy, *Defining the Contours of the Emerging Fraudulent Misjoinder Doctrine*, 29 Harv. J.L. & Pub. Pol'y 569 (2006).

Still more disagreement exists over whether to analyze alleged fraudulent misjoinder with reference to the state or the federal procedural rule governing permissive joinder of parties. In *Tapscott*, the Eleventh Circuit analyzed the issue with reference to the federal rule, noting that the state procedural rule was identical to the federal one. *Id.* at 1355 n.1. The court in *Stephens* proceeded the same way, noting that "Maryland's law governing permissive joinder is substantively identical to its federal counterpart and need not be considered independently." 807 F. Supp. 2d at 381 n.5. Other courts, however, "have determined that the issue of whether claims have been misjoined should be evaluated under state procedural law rather than federal law." *Asher v. Minnesota Mining & Mfg. Co.*, Civ. No. KKC-04-522, 2005 WL 1593941 (E.D. Ky. June 30, 2005) (collecting cases); *see Osborn v. Metropolitan Life Ins. Co.*, 341 F. Supp. 2d

1123, 1128 (E.D. Cal. 2004) ("[M]ost courts looking at this issue have applied the state rule. This seems the better choice since the question is whether the parties were misjoined in state court."). This debate is not merely academic, as some states' joinder rules are more permissive than the federal rule. *See, e.g.*, *Osborn*, 341 F. Supp. 2d at 1128–29 ("California joinder rules have been construed liberally and there are situations where the State's joinder rules would allow for permissive joinder of defendants while the federal rules would not."); *Jamison v. Purdue Pharma Co.*, 251 F. Supp. 2d 1315, 1320 (S.D. Miss. 2003) ("This situation presents a dilemma for a district court confronted with a removed case consisting of parties who are properly joined under Mississippi's Rule 20, but misjoined under that rule's federal counterpart.").

Fortunately, I need not enter this doctrinal thicket. Even if I adopted the fraudulent misjoinder doctrine, despite its flaws,[8] applying it to sever the claims in this case would turn the doctrine entirely on its head.

As discussed, the doctrine was created to prevent unscrupulous plaintiffs from improperly joining non-diverse parties in a fraudulent attempt to avoid a federal forum. That is not what happened in this case. Here, for more than a year, plaintiff initially proceeded only against the Medical Defendants. Most of the Medical Defendants are citizens of Maryland. Therefore, from the outset, there was no diversity jurisdiction, nor any possibility of removal to federal court.

[8] For a discussion of the possibility that the doctrine violates Fed. R. Civ. P. 82, *see Jamison*, 251 F. Supp. 2d at 1321 n.6. For a discussion of the possibility that the doctrine contravenes congressional intent, *see* Ronald A. Parsons, Jr., *Should the Eighth Circuit Recognize Procedural Misjoinder?*, 53 S.D. L. Rev. 52, 62–64 (2008). For a discussion of the uncertainty the doctrine has engendered, *see Osborn*, 341 F. Supp. 2d at 1126–28. For a discussion of the federalism concerns the doctrine raises, *see Rutherford v. Merck & Co., Inc.*, 428 F. Supp. 2d 842, 852, 854 (S.D. Ill. 2006).

Thereafter, plaintiff re-filed her suit, adding the Pharmaceutical Defendants to the case. The decision to add the Pharmaceutical Defendants, far from being a fraudulent attempt to defeat diversity, actually opened the door to the possibility of a federal court hearing the matter. Although the Pharmaceutical Defendants may have been added to the case "[o]n the eve of trial," Notice of Removal ¶ 2, their addition was not an eleventh hour effort to avoid a federal forum. Thus, the circumstances of this case are not in the same ballpark, the same league, or even the same sport as those which necessitated the creation of the fraudulent misjoinder doctrine.

In any event, regardless of plaintiff's motive in joining the Pharmaceutical Defendants and the Medical Defendants, the joinder is entirely proper. Both the federal and Maryland state joinder rules permit joinder of defendants if "any right to relief is asserted against them . . . arising out of the same transaction [or] occurrence" and "any question of law or fact common to all defendants will arise in the action." Fed. R. Civ. P. 20; *see* Md. Rule 3-212. As the Maryland Court of Appeals has said, "'The core purpose of the rule is to permit a single trial of claims having a similar foundation or similar issues.'" *Kennedy v. Lasting Paints, Inc.*, 404 Md. 427, 444, 947 A.2d 503, 513 (2008) (quoting Paul D. Niemeyer & Linda M. Schuett, *Maryland Rules Commentary* 143–44 (3d ed. 2003)).

Both prongs of the joinder inquiry are easily satisfied here. As to the first prong, the genesis of this suit involves a series of "transactions or occurrences," *i.e.*, Mr. Larson's ingestion of HUMIRA. As to the second prong, there are several common questions of fact between the

two sets of defendants, including the propriety of prescribing HUMIRA to an HIV+ person for the treatment of psoriasis.[9]

Indeed, it would be exceedingly inefficient, if not problematic, if Ms. Larson chose *not* to join the Pharmaceutical Defendants and the Medical Defendants in one suit. A jury determining whom to hold liable for Mr. Larson's injuries surely needs to hear from both sets of defendants. If the negligence and product liability claims were tried separately, each set of defendants "could utilize the 'empty chair' defense," conveniently blaming the injuries on the missing defendants. *Stephens*, 807 F. Supp. 2d at 384. As one court has observed, *Rice v. Pfizer, Inc.*, No. 06-0757, 2006 WL 1932565 at *3 (N.D. Tex. July 7, 2006): "If the Pharmaceutical Defendants prove that they provided adequate warning to physicians and/or the public . . . then [the doctor] may be liable for medical malpractice because he knew or should [have] known of the risks based on the Pharmaceutical Defendants' warning." On the other hand, if the Pharmaceutical Defendants did not inform physicians of HUMIRA's risks, then perhaps the Medical Defendants would be held blameless. Either way, "the defendants will almost certainly debate which defendant is most responsible for the injuries . . . , the extent of the injuries, and what caused the injuries." *Wyatt v. Charleston Area Med. Ctr., Inc.*, 651 F. Supp. 2d 492, 498 (S.D. W. Va. 2009).

In addition, if plaintiff were to proceed separately against each group of defendants, it is quite possible that each group of defendants would file third party claims against the persons or entities in the other group. This would return the case to the pre-severance posture.

[9] Arguably, the allegations against Dr. Yang and Annapolis Infectious Disease Associates, L.L.P. most resemble a classic medical malpractice claim. However, the claims against Dr. Meltzer are clearly connected to the claims against the Pharmaceutical Defendants.

What is more, severing the claims would result in precisely that which the liberal joinder rules were meant to prevent. By ensuring that claims presenting similar issues are tried together, the joinder rules "'promote trial convenience and expedite the final determination of disputes, thereby preventing multiple lawsuits.'" *Saval v. BL, Ltd.*, 710 F.2d 1027, 1031 (4th Cir. 1983) (quoting *Mosley v. General Motors Corp.*, 497 F.2d 1330, 1332 (8th Cir. 1974)). Severing the claims here would require Ms. Larson to proceed on separate and redundant tracks in federal and state court, which would "result in the duplication of evidence, increase the cost of litigation, and carries with it the potential for inconsistent verdicts." *Reuter v. Medtronics, Inc.*, No. 10-3019, 2010 WL 4628439 (D.N.J. Nov. 5, 2010), *report and recommendation adopted*, 2010 WL 4902662 (D.N.J. Nov. 23, 2010).

The majority of federal courts that have addressed joinder in the context of jointly pled medical malpractice and product liability claims have reached the same conclusion. *See, e.g.*, *Ramirez v. Our Lady of Lourdes Hosp. at Pasco*, No. 13-01108, 2013 WL 5373213 (W.D. Wash. Sept. 25, 2013); *Nolan v. Olean Gen. Hosp.*, No. 13-333, 2013 WL 3475475 (W.D.N.Y. July 10, 2013); *Goodwin v. Kojian*, No. 13-325, 2013 WL 1528966 (C.D. Cal. Apr. 12, 2013); *N.C. ex rel. Jones v. Pfizer, Inc.*, No. 12-00531, 2012 WL 1029518 (N.D. Cal. Mar. 26, 2012); *Hagensicker v. Boston Scientific Corp.*, No. 12-5018, 2012 WL 836804 (W.D. Mo. Mar. 12, 2012); *Yates v. Medtronic, Inc.*, No. 08-0337, 2008 WL 4016599 (S.D. Ala. Aug. 26, 2008); *Snyder v. Davol, Inc.*, No. 07-1081, 2008 WL 113902 (D. Or. Jan. 7, 2008); *Greene v. Novartis Pharm. Corp.*, No. 07-00091, 2007 WL 3407429 (M.D. Ga. Nov. 14, 2007); *Moote v. Eli Lilly*

and Co., No. 06-472, 2006 WL 3761907 (S.D. Tex. Dec. 21, 2006); *Jamison, supra*, 251 F. Supp. 2d 1315. *But see In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, No. 07-1487, 2007 WL 2572048 (D. Minn. Aug. 30, 2007).

Accordingly, I will not sever the Medical Defendants from the suit. Because the Medical Defendants are citizens of the same state as the plaintiff, complete diversity does not exist. It follows that this Court lacks diversity jurisdiction.[10]

CONCLUSION

For the foregoing reasons, I conclude that this Court lacks subject matter jurisdiction as to this case. Accordingly, pursuant to 28 U.S.C. § 1447(c), the case must be remanded to the Circuit Court for Baltimore City for further proceedings. An Order implementing this ruling follows.

Date: November 5, 2013

/s/
Ellen L. Hollander
United States District Judge

[10] Even if Ms. Larson were determined to be a citizen of New Jersey, *see* Complaint ¶ 3, removal of the suit as it currently exists would still be improper, because some of the Medical Defendants are citizens of Maryland, and a case "may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2). Thus, the case is not removable on the basis of diversity.